

# Missouri Statewide Health Information Exchange

## Legal/Policy Workgroup

Jefferson City, MO  
December 3, 2009



# Agenda

Topic	Facilitator(s)	Time
Welcome & Introductions	Co-Chairs	15 minutes
HIE & HITECH Opportunities	Co-Chairs & Manatt	15 minutes
Project Overview <ul style="list-style-type: none"><li>➤ Workgroup Framework</li><li>➤ Timeline</li><li>➤ Tasks</li></ul>	Co-Chairs & Manatt	20 minutes
Strategic Plan Components	Co-Chairs & Manatt	15 minutes
Considerations & Key Questions	Co-Chairs	40 minutes
Next Steps	Co-Chairs & Manatt	15 minutes

# Welcome & Introductions

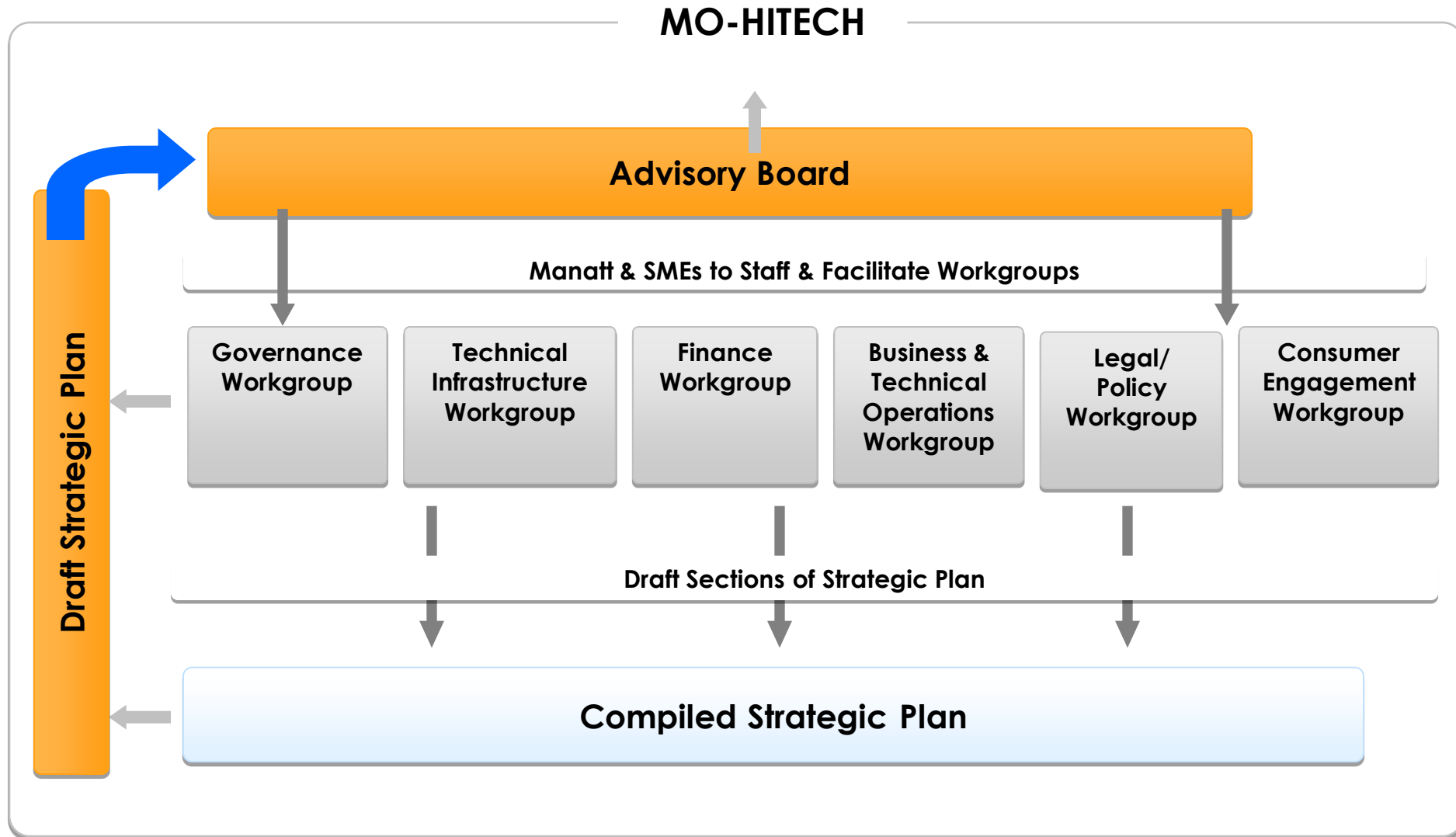
## ➤ Co-Chairs

- Sandy Johnson, Professor Emerita of Law and Health Care Ethics, St. Louis University School of Law
- Doug Nelson, Deputy Commissioner/General Counsel, Office of Administration, State of Missouri

## ➤ Staff

- Laurie Hines, Special Assistant, Department of Health and Senior Services
- Melinda Dutton, Partner, Manatt Health Solutions
- Helen Pfister, Partner, Manatt Health Solutions
- Alice Lam, Senior Analyst, Manatt Health Solutions

# Building the Strategic Plan – Workgroup Framework



# Project Tasks & Timeline through May 2010

## State HIE Grant Application

Letter of Intent Submitted

Project Initiation

Begin Landscape Assessment & Interviews

Sept Oct

- Support State application process
- Conduct stakeholder interviews

## Strategic Plan

Submit Application to HHS

Executive Order 09-27

Statewide Kickoff Meeting

Nov Dec Jan 2010 Feb

- Establish MO-HITECH
- Establish Advisory Board
- Convene Workgroups
- Draft Strategic Plan
- Publish Draft Strategic Plan for Review
- Develop detailed project timeline and work plan
- Engage and educate stakeholders

Submit Strategic Plan to HHS

Publish Draft Strategic Plan for Review/Comment

## Operational Plan

Submit Operational Plan to HHS

Publish Draft Operational Plan for Review/Comment

Mar April May

- Convene Advisory Board & Workgroups
- Draft Operational Plan
- Publish Draft Operational Plan for Review
- Update project timeline and work plan
- Engage and educate stakeholders

# Building the Strategic Plan –Draft Timeline

Weeks	Planning	Kickoff		First Draft	Final Draft	
Nov 9	Confirm AB membership					
Nov 16	Announce Wkgps & Kickoff Meeting					
Nov 23	Finalize Kickoff Meting Materials					
Nov 30	AB – Advisory Board Wkgps – Workgroups Subject Matter Experts – SMEs	Launch AB - 12/2	Launch Wkgps -12/3			
Dec 7				Workgroups Meet Regularly & Prepare 1 <sup>st</sup> Draft of Deliverables		
Dec 14				Manatt & SMEs to Advise WKgps		
Dec 21				Draft due to Manatt & MO-HITECH: 12/23		
Dec 28				Manatt to Compile First Draft		
Jan 4 2010				First Draft distributed to MO-HITECH & AB		
Jan 11				AB to review First Draft		
Jan 18					Wkgps to Revise First Draft	
Jan 25					Manatt & SMEs to advise Wkgps	
Feb 1					Drafts due to Manatt & MO-HITECH: Feb 5	
Feb 8					Manatt to compile revised Draft & distribute to Mo-HITECH & AB	
Feb 15					AB to review revised Draft	
Feb 22					Manatt & MO-HITECH to make final revisions	
					Finalize & Submit Strategic Plan	

# Building the Strategic Plan – Advisory Board and Workgroup Tasks

- **Week of November 30th: Kickoff**
  - Launch Advisory Board (December 2<sup>nd</sup>)\*
  - Host statewide kickoff meeting (December 2<sup>nd</sup> & 3<sup>rd</sup>)
  - Identify key deliverables and timeline
  - Identify workgroup leadership/co-chairs
  - Assign tasks (e.g. writing, research)
- **November 30<sup>th</sup> – December 23<sup>rd</sup>: First Draft**
  - Workgroups to meet weekly or bi-weekly (as determined necessary)
  - Draft Strategic Plan content & circulate for review
  - Incorporate workgroup revisions and feedback
  - Submit for incorporation into first draft
- **December 23<sup>rd</sup> – January 15<sup>th</sup> : Fill in Gaps**
  - Work with Manatt & subject matter experts to address gaps in first draft
  - Review Advisory Board & MO-HITECH feedback
- **January 15<sup>th</sup> – February 5<sup>th</sup>: Second Draft**
  - Revise Strategic Plan content based on Advisory Board & MO-HITECH feedback
  - Submit for incorporation into second draft
- **February 5<sup>th</sup> – February 28<sup>th</sup>: Finalize Strategic Plan**
  - Workgroup Co-Chairs to work with Manatt & subject matter experts to finalize Strategic Plan content
  - Submit Strategic Plan to ONC (Target submission date: February 28, 2010)

# Building the Strategic Plan: Workgroups

- **Led by appointed Co-Chairs**
- **Open membership**
- **Staff supported**
- **Areas of focus**
  - Governance
  - Finance
  - Technical Infrastructure
  - Business & Technical Operations
  - Legal/Policy/Privacy
  - Consumer Engagement
- **Meetings & frequency**
  - Kickoff meeting: December 3<sup>rd</sup>, Jefferson City
  - Workgroups will meet weekly or bi-weekly following kickoff meeting (as necessary)
  - Meetings will be accessible via teleconference, but in-person participation is recommended; all meetings will take place in Jefferson City



# State HIE Grant Application: MO-HITECH Cooperative Agreement Program

- **Submitted to ONC on October 16<sup>th</sup>**
- **Proposed project will:**
  - Develop a Strategic and Operational Plan to support the development of HIE capacity and infrastructure among Missouri's health care providers
  - Be overseen by a public-private Advisory Board that will provide guidance to MO-HITECH
  - Convene collaborative public stakeholder Workgroups to inform strategy development around the key areas of
    - Governance
    - Technical infrastructure
    - Finance
    - Business and technical operations
    - Legal/Policy
    - Consumer Engagement
  - Identify how the State may leverage existing regional HIE and health IT investments, as well as investments that the State has made in its technical infrastructure
  - Be closely coordinated with Medicaid and public health stakeholders to ensure that providers of underserved populations are able to participate in HIE and achieve meaningful use of EHRs

# State HIE Grant Application: Legal/Policy

- The Legal/Policy Workgroup will be charged with
  - Establishing a statewide policy framework and process to oversee the development of policies to facilitate statewide HIE and protect health information as required by state and federal laws
  - Identifying a process to work toward harmonizing federal and state legal and policy requirements to support HIE.
  - Developing a framework to assess the implications of cross-border HIE and identify a process to resolve potential conflicts
  - Addressing enforcement mechanisms and the agreements necessary to ensure the appropriate oversight and accountability among HIE participants

# Legal/Policy/Privacy & Security

**Developing the statewide policies, practices, and enforcement mechanisms to protect the privacy of patient health information.**

## ONC's Achievements Expected by 2011

- **Harmonization:** Identify and harmonize legal and policy requirements that enable appropriate HIE.
- **Statewide Policy Framework:** Establish a statewide policy framework that allows incremental development of HIE policies over time.
- **Enforcement:** Implement enforcement mechanisms that ensure appropriate safeguards are in place and adherence to legal and policy requirements.
- **Common Approaches:** Minimize obstacles in data sharing agreements (e.g., developing accommodations to share risk and liability of HIE operations).
- **Implementation and Evaluation:** Ensure policies and legal agreements are implemented and evaluated as a part of annual program evaluation.

# Building the Strategic Plan: Workgroup Deliverables

Workgroup	Deliverables
<b>Governance</b>	<ul style="list-style-type: none"> <li>➤ Description of governance entity including membership, authority, and governance model</li> <li>➤ Description of how state will address HIE accountability and transparency</li> <li>➤ Description of coordination with Medicaid, federally-funded state programs, and other ARRA programs (e.g. broadband)</li> </ul>
<b>Finance</b>	<ul style="list-style-type: none"> <li>➤ Business plan that enables financial sustainability of HIE governance and operations by 2014</li> <li>➤ Develop and update project budget</li> </ul>
<b>Technical Infrastructure</b>	<ul style="list-style-type: none"> <li>➤ Description of how infrastructure will facilitate interoperability</li> <li>➤ Description of technical approach and architecture to be used including HIE services to be offered (<i>if applicable</i>)</li> <li>➤ Review and augment environmental scan of HIE</li> </ul>
<b>Business &amp; Technical Operations</b>	<ul style="list-style-type: none"> <li>➤ Implementation strategy to address how the state will meet meaningful use requirements</li> <li>➤ Description of incremental approach for HIE services to reach all geographies and providers</li> <li>➤ Identify plan and timeline for NHIN participation</li> </ul>
<b>Legal/Policy</b>	<ul style="list-style-type: none"> <li>➤ Describe MO and interstate privacy and security issues related to HIE</li> <li>➤ Describe plans to analyze and/or modify state laws</li> <li>➤ Describe development of policies and procedures to foster HIE</li> <li>➤ Describe the use of trust agreements (e.g. data sharing and use agreements)</li> <li>➤ Describe how the state will address noncompliance with HIE policies</li> </ul>
<b>Consumer Engagement</b>	<ul style="list-style-type: none"> <li>➤ Consumer engagement and outreach plan</li> <li>➤ Develop communications and educational materials for consumers, general public, and press</li> </ul>

# Building the Operational Plan: Workgroup Deliverables

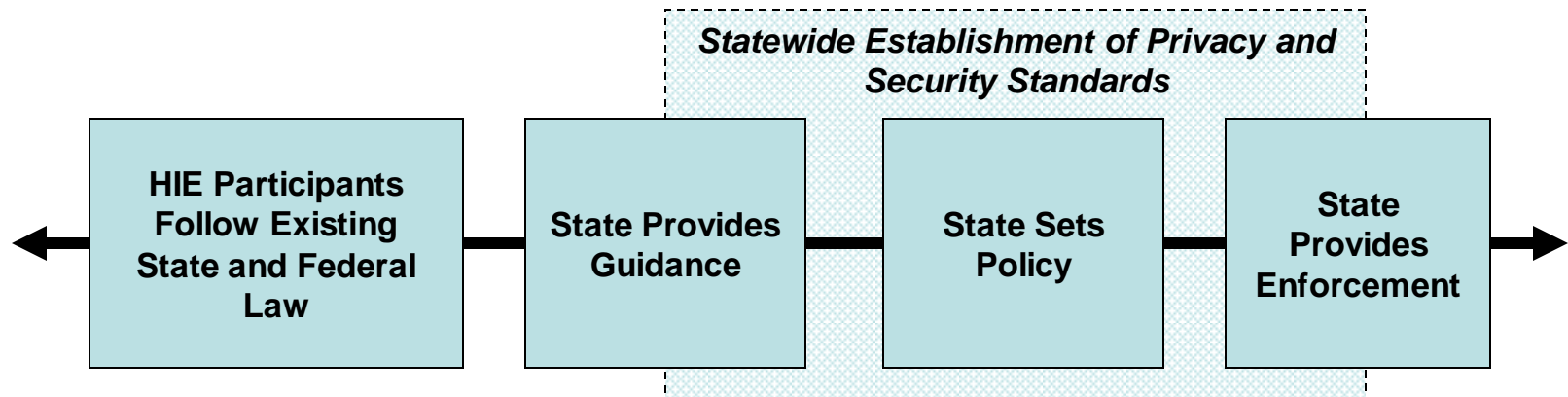
Workgroup	Deliverables
<b>Governance</b>	<ul style="list-style-type: none"> <li>➤ Description of coordination and interdependencies with relevant ARRA programs (e.g. REC, broadband, and workforce development)</li> <li>➤ Description of governance and policy structures, including their ongoing development</li> </ul>
<b>Finance</b>	<ul style="list-style-type: none"> <li>➤ Detailed cost estimate for the implementation of the Strategic Plan</li> <li>➤ Detailed schedule describing the tasks and sub-tasks to be completed, including resources, dependencies, and specific timeframes</li> <li>➤ Description of proposed resolution and mitigation methods for identified issues and risks</li> <li>➤ Staffing plans for the project, including project managers and description of key roles</li> <li>➤ Description of activities to implement financial policies, procedures, and controls to ensure compliance with GAAP and OMB Circulars</li> </ul>
<b>Technical Infrastructure</b>	<ul style="list-style-type: none"> <li>➤ Description of efforts to become consistent with HHS adopted interoperability standards and certification requirements as part of the planned implementation</li> <li>➤ Description of the technical architecture and how its requirements will ensure statewide availability of HIE among healthcare providers, including plans for protection of health data</li> <li>➤ Description of how the technical architecture will align with NHIN core services and specifications</li> <li>➤ Description of technical solutions to develop HIE capacity and enable meaningful use</li> </ul>
<b>Business &amp; Technical Operations</b>	<ul style="list-style-type: none"> <li>➤ Project schedule describing tasks and sub-tasks to be completed to enable statewide HIE</li> <li>➤ Identification and description of issues, risks, and interdependencies within the overall project</li> <li>➤ Description of how the state will leverage current HIE capacities</li> <li>➤ Description of state-level shared services and repositories to be leveraged (if applicable)</li> <li>➤ Explanation of standard operating procedures and processes for HIE services will be developed and implemented (not required)</li> </ul>
<b>Legal/Policy</b>	<ul style="list-style-type: none"> <li>➤ Description of how statewide HIE will comply with applicable federal and state legal policy requirements, including the process for developing and implementing policy requirements</li> <li>➤ Description of interdependence of governance and oversight mechanisms</li> <li>➤ Description of plans for privacy and security harmonization and plans for interstate coordination</li> <li>➤ Address how state will comply with federal requirements for data protection</li> </ul>
<b>Consumer Engagement</b>	<ul style="list-style-type: none"> <li>➤ Consumer engagement and outreach plan</li> <li>➤ Communication messages and educational deliverables for dissemination</li> </ul>

# Strategic Plan Timeline & Deliverables

Legal/ Policy	Strategic Plan
<b>Charge</b>	<ul style="list-style-type: none"> <li>➤ Establish framework for trust and accountability that protects the privacy and security of health information</li> <li>➤ Support consumer control and access to personal health information</li> <li>➤ Identify practical privacy and security strategies and policies to support secure HIE</li> <li>➤ Identify operational and environmental processes to support privacy and security policies</li> <li>➤ Contribute to consumer engagement/education and outreach strategy</li> </ul>
<b>Deliverables</b>	<ul style="list-style-type: none"> <li>➤ Describe MO and interstate privacy and security issues related to HIE</li> <li>➤ Describe plans to analyze state laws</li> <li>➤ Describe development of policies and procedures to foster HIE</li> <li>➤ Describe the use of trust agreements (e.g. data sharing and use agreements)</li> <li>➤ Describe how the state will address noncompliance with HIE policies</li> </ul>
<b>Tentative Timeline (Week(s) of)</b>	<ul style="list-style-type: none"> <li>➤ Dec 2 &amp; 3: Attend Statewide Kickoff Meeting to review &amp; confirm Workgroup charge; distribute assignments</li> <li>➤ Dec. 9: Provide comments and feedback on threshold questions (above) to Workgroup staff and co-chairs; please send feedback to <a href="mailto:kwallis@manatt.com">kwallis@manatt.com</a></li> <li>➤ Dec. 14: Workgroup meeting to review collected feedback</li> <li>➤ Dec. 23: First draft due to MO-HITECH &amp; Manatt</li> <li>➤ Jan. 8: Manatt to distribute feedback/questions to Workgroup</li> <li>➤ Jan. 11: Review draft Strategic Plan sent to Advisory Board</li> <li>➤ Jan. 18 – Feb. 5: Revise draft Strategic Plan components based on Advisory Board &amp; MO-HITECH feedback</li> <li>➤ Feb. 5: Workgroup to submit updated draft</li> <li>➤ Feb 5 - 28: Workgroup to meet ad hoc to address questions and revise Strategic Plan Content</li> </ul>
<b>Co-Chairs</b>	<p>Sandy Johnson, Professor Emerita of Law and Health Care Ethics, St. Louis University School of Law</p> <p>Doug Nelson, Deputy Commissioner/General Counsel, Office of Administration, State of Missouri</p>
<b>Staff</b>	<p>Laurie Hines, Special Assistant, Department of Social Services</p> <p>Melinda Dutton, Partner, Manatt Health Solutions</p> <p>Helen Pfister, Partner, Manatt Health Solutions</p> <p>Alice Lam, Senior Analyst, Manatt Health Solutions</p>

# Privacy & Security: Continuum

- What is the State's role in defining privacy and security policies for HIE in Missouri?



# Health Information Exchange

## Changing the Privacy Paradigm

### Today

#### “One-to-One” Exchange

- Human judgment plays a critical role in determining what information is shared and with whom
- Phone conversations between clinicians for purposes of treatment frequently replace the need for physically exchanged information.
- Authentication of requests for information is heavily reliant on relationships between organizations or individuals charged with information sharing.

### Tomorrow

#### “Many-to-Many” Exchange

- In an environment of ubiquitous electronic HIE, data will be gathered or transferred between multiple entities without benefit of the familiar relationships of the old paradigm.
- At the time of collecting the data, verification of the requester and sources will be critical, and may require sophisticated permission and authorization controls.



# Health Information Exchange

## Core Questions for Privacy and Security Policies

Provider Access to Information



- Should *any* provider have unrestricted access to all information without consent for treatment purposes?
- Is provider access limited to treatment, or does it include other uses – quality assurance, care management, research, etc.?

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Payer Access to Information



- Should payers have unrestricted access to information without consent, or should it be restricted to care management for patient benefit?

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Consumer Access to Information



- Do we want to require consumer access to information?

# Health Information Exchange

## Governance and Privacy Framework

Who sets the rules?



- Local level – too small to have meaningful policies
- State level – right for scale and enforceability
- Federal level – run the risk of ambiguity

What are the rules?



- What do federal and State laws require?
- What are the policy choices being made by governing authority?

Who enforces the rules?



- Enforced through a RHIO governance model and/or contractual model?
- State/federal regulators?

# Considerations

- Privacy and Security policies may include authentication, authorization, access controls and audit (the “four A’s”).
- Federal requirements under HIPAA serve as a national floor for privacy and security, with Missouri state law layering on top.
  - Confidentiality
  - Patient consent
  - Unemancipated minors
  - Sensitive patient health information
- Existing privacy and security requirements must be assessed in light of statewide electronic HIE.
- A collaborative governance process involving broad stakeholder representation is required to resolve threshold issues
- State government blessing of any statewide policies developed as compliant with existing law can protect HIE participants from liability as a result of following policy and ensure participation of state programs including Medicaid.

# Discussion Questions

- What work has been done to date to understand Missouri privacy and security policies relative to health information exchange?
  - How may that work be leveraged?
  - What are the gaps and how will additional work be accomplished?
- What should the role of the State be in developing statewide privacy and security policy guidance?
- What should the process be for developing comprehensive statewide policy guidance with respect to privacy and security issues?
- What level of agreement exists on the core issues that must be addressed to ensure privacy and security of health information in the context of statewide HIE?
- How should Missouri ensure adherence to the legal, business, and technical rules developed through the statewide process?
- How will the state pursue harmonizing policies with neighboring states to enable interstate HIE?

# Next Steps

- **Review Application & Project Narrative**
  - <http://dss.missouri.gov/hie/files/pca-project-narrative.pdf>
- **Review Strategic Plan requirements**
  - Funding Opportunity Announcement:  
[http://healthit.hhs.gov/portal/server.pt?open=512&objID=1336&parentname=CommunityPage&parentid=2&mode=2&in\\_hi\\_userid=10741&cached=true](http://healthit.hhs.gov/portal/server.pt?open=512&objID=1336&parentname=CommunityPage&parentid=2&mode=2&in_hi_userid=10741&cached=true)
- **Identify additional stakeholders for future Workgroup participation**
- **Review identified tasks and assignments**
- **Submit feedback and comments on discussion questions by December 9<sup>th</sup> to [kwallis@manatt.com](mailto:kwallis@manatt.com)**
- **Next Meeting: December 15<sup>th</sup> or 16<sup>th</sup> (Date & Time TBD)**
  - 205 Jefferson St, Jefferson City MO 10th floor Conference Room B

# Appendix

# Privacy & Security – Threshold Issues Must Be Agreed Upon to Develop Statewide P&S Policies

	Issue	Background	Threshold Decision	Implication
1	<b>Statewide Collaboration</b>	Privacy & security policies must be informed by the viewpoints and experiences of all of those who will be subject to their regulation.	Agreement that a collaborative governance process involving broad stakeholder representation is required to resolve these threshold issues and other, less foundational, though no less important issues.	Without a statewide, collaborative process in place that includes the right stakeholders and is funded appropriately, it may not be possible to develop statewide privacy & security policies
2	<b>Scope</b>	<p>While HIPAA does not require consent for treatment and other specific uses of health information, it is important to remember that HIPAA was written in the context of a one-to-one health information exchange environment.</p> <p>An interoperable health system facilitates a many-to-many information exchange relationship that, some believe, may demand new approaches for protecting privacy and security.</p> <p>Many-to-many exchange allows for health care providers to reach out to large networks of clinicians and providers to obtain health information and use it in patient care</p>	Agreement as to whether or not any new statewide privacy and security policies should be applied <i>only</i> to HIE occurring through a statewide health information network and not to existing one-to-one exchanges.	Decisions about level of protection afforded to health information exchanged in MO should only be contemplated after this threshold decision is made.

# Threshold Privacy & Security Issues (Continued)

	Issue	Background	Threshold Decision	Implication
3	<b>Policy Interoperability</b>	Statewide policies are necessary to obtain patient trust and ensure interoperability. To protect privacy & security, policies must be enforced at the state-level and cannot be set locally by different HIE projects.	Agreement as to whether or not all participants in statewide HIE will be required to abide by the privacy & security policies under development and whether a statewide enforcement mechanism will be in place to ensure compliance.	Statewide policies related to privacy & security that must be followed by all providers exchanging information in MO will have a significant impact on any technical specifications imposed to ensure interoperability throughout the state.
4	<b>Compliance with Existing Law</b>	Federal and state laws may, for instance, require special protections be granted to certain classes of information (e.g. laws requiring consent for disclosure of records of federally-assisted substance abuse centers).	<p>Agreement as to whether or not statewide privacy and security policies will be adopted in compliance with existing law or whether changes in existing law will be sought.</p> <p>Further agreement that MO state government will bless any statewide policies developed as compliant with existing law so as to ensure HIE participants are not subject to liability as a result of following policy.</p>	A decision to adopt policies in compliance with existing law will impose certain limitations that must be accepted.



# Threshold Privacy & Security Issues (Continued)

	Issue	Background	Threshold Decision	Implication
5	<b>Baseline Access Principle(s)</b>	Owing to sensitivity related to certain types of Protected Health Information (e.g. information related to minors, HIV/AIDS status, mental health, substance abuse and genetic testing), some HIEs may choose to filter, or treat specially, such information from exchange.	Agreement as to whether those involved in health information exchange will be required/allowed to filter certain types of sensitive health.	A decision to require/allow for filtering of certain types of Protected Health Information will necessitate development of specialized policies and technical capabilities.
6	<b>Baseline Consent Principle(s)</b>	In order to ensure that Protected Health Information is available and ready for sharing when a provider seeks to access it through a health information exchange, information may be uploaded to a HIE/otherwise be made available in advance of the provider request.	Agreement as to whether consent will be required in order to ready it for exchange by uploading it to a HIE.	How this decision is addressed will impact the availability of data and the general utility of the exchange.